K033475

JAN - 7 2004

## SECTION 2 - 510(K) SUMMARY

**Name and Address of Applicant**
Nihon Kohden America, Inc.
Attn: Regulatory Affairs
90 Icon Street
Foothill Ranch, California 92610
Phone: (949) 580-1555
Fax: (949) 580-1550

November 2, 2003

Trade name: Wireless Input Unit
Common Name: Electroencephalograph
Classification: II
The Predicate: Siesta system by Compumedix, 510K No: K003175

The device is classified by the Neurology Panel under 21 CFR Part 882.1400 "Electroencephalograph" per GWQ.

The device is intended to record, measure and display the physiological data required for EEG and sleep studies as an aid in diagnosis. The product is comprised of telemetry unit, Electrode junction box and access point to operate with our current commercially available EEG devices. The basic measurement data includes: EEG, EOG, ECG, EMG, respiration, periodic limb movement (PLM), snore, $S_PO_2$ and sleep position.

This device is intended for use by medical personnel and will be available for use within a medical facility or outside of a medical facility under direct supervision of a medical professional.

The device does not directly contact patients. New accessories that contact patients such as the EEG electrodes are made from the same component materials as similar legally marketed accessories. Therefore, good laboratory practice studies were not required per 21 CFR part 58. Electrodes and sensors from the patient are connected to telemetry unit through the electrode junction box. The telemetry unit communicates with Nihon Kohden Access point, ZR-101AA. The Access point is connected to other cleared Nihon Kohden EEG machines for all previously cleared indications of monitoring patients' physiological data.

The device is not sterile.

The device was developed in accordance with design controls and operation of the device was appropriately verified and validated using the same test methods as with the existing device.

The device technological characteristics are the same as predicate. The device Risk analysis and summary of Validation/Verification are attached.

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## SECTION 3 - PROPOSED LABELING

**A. Intended Use**

The device, a multi-functional ambulatory recording device, is intended for medical purposes to store, record, measure and display cerebral and extracerebral activity for EEG and Sleep Studies. These data, may be used by the clinician in Sleep Disorders, Epilepsies and other related disorders as an aid in diagnosis. This is the same intended use as previously cleared for the EEG-1100A, and EEG-9100A ( per K992742 and K 011204) as well as Siesta system (predicate).

**B. Device/Package Labels**

The proposed labels for the device are located in Attachment # 4.

**C. Proposed Packaging**

Packaging is similar to the packaging for the existing marketed device and is included in Attachment # 4.

**D. Instructions for Use**

The proposed instructions for use, including warnings and cautions, are provided with each packaged device and a draft is presented in Attachment # 2.

**E. Advertisement/Promotional Literature**

To date, no advertisement or promotional literature for the new device options has been created for distribution in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2004

Ms. Serrah Namini
Regulatory Affairs Associate Director
Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, California 92610

Re: K033475
Trade/Device Name: Wireless Input Unit; WEE-1000A Series
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: November 1, 2003
Received: November 3, 2003

Dear Ms. Namini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K033475

Device Name: Wireless Input Unit; WEE-1000A series

Indications For Use:

The device is intended to acquire, store, and transfer biophysical parameters to EEG machines for the purpose of assisting the diagnosis of neurological and sleep disorders, measurement and display of cerebral and extracerebral activity for EEG and Sleep Studies. These data, may be used by the clinician in Sleep Disorders, Epilepsies and other related disorders as a diagnostic tool.

The device is intended for use by medical personnel in any location within a medical facility, physician's office, laboratory, clinic or nursing home or outside of a medical facility under supervision of a medical professional. The device will be available on all patient populations, including pediatrics.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices



510(k) Number K033475